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Serial N°: 10/502,078
Filed : July 20, 2004
Title : Orodispersible pharmaceutical composition of piribedil
Art Unit : 1615
Examiner : Pili A. HAWES Esq.

Honorable Commissioner of Patents
PO BOX 1450
Alexandria, VA 22313

DECLARATION UNDER 37 CFR 1.132

I, Marc JULIEN, a citizen of France, of 117, route de Marmain, 45110 SIGLOY, France, declare and say that :

I hold the degree of DUT of chemistry (1984) from the University of ORLEANS (France).

Since 1985, I have been technician at the Institut de Recherches Servier, France.

I am the author or co-author of more than nine international publications such as patents, scientific publications and communications.

I am one of the co-inventors of US Patent Application Serial n° 10/502,078 filed July 20, 2004 concerning "Orodispersible pharmaceutical composition of piribedil".

I am thoroughly familiar with the above-mentioned patent application and fully support the chemical data contained therein which were performed either by me or under my supervision. I also fully support the conclusions derived and the arguments presented as concerns the therapeutic interest and utility of the compounds described.

The compounds of the present invention have pharmacological and galenic properties which allow their use in the long-term treatment and treatment of acute episodes of Parkinson's disease.

The compounds disclosed in the present application (US Serial 10/502,078) have demonstrated marked activity in the following galenic tests :

Comparative Test of friability and disintegration

Formula of pharmaceutical composition :

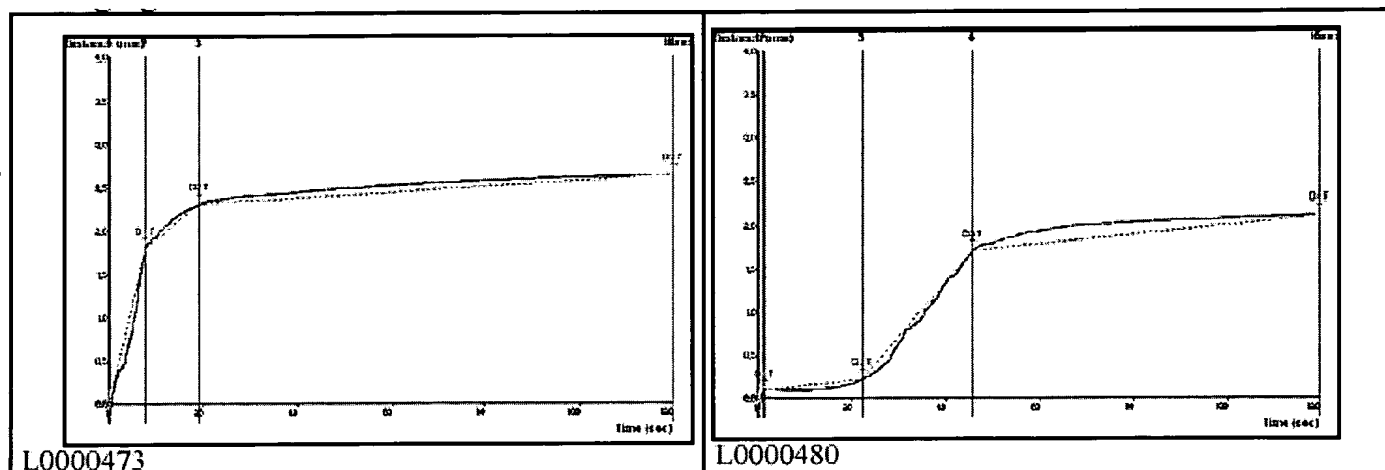
	S9490	Starlac	Tablettose	Starch 1500	Mass of tablet
Invention	5	95			100
Control	5		80	15	100

Tablettose : monohydrated lactose 85%

Starch 1500 : gelatinized corn starch 15%

Results :

Parameters	Methods	L0000473	L0000480
Hardness	Schleuniger 4M European Pharmacopoeia 2.9.8	Average 16N Maxi 18N Mini 14N	Average 15N Maxi 18N Mini 13N
Friability	Mixer European Pharmacopoeia 2.9.7	2.1%	1.1%
Disintegration in vitro	European Pharmacopoeia	Average 5 sec Maxi 7 sec Mini 3 sec	Average 18 sec Maxi 21 sec Mini 17 sec
Disintegration in vitro	Texturometer TAXT Plus	graph	graph



Tablets comprising Starlac have orodispersible features (rapid disintegration and dispersion of powder without formation of a core). Starlac induces instantaneous disintegration of the tablets. To the contrary, tablets comprising starch and tablettose have latency time of 22' before the beginning of disintegration.

Equivalent results are obtained with other active ingredients in view of the proportion (5 to 25%) of said active ingredients in the pharmaceutical composition. Active ingredients have no effect on disintegration features. Disintegration is exclusively bound to amount and combination of co-dried lactose and starch in granules in Starlac.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of the title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Further declarant sayeth not

Marc JULIEN

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke at the bottom.

Executed at : Orléans

Date : 22 . 2 . 06

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